REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 11 and 15-20 remain pending in the application subsequent to entry of this Amendment.

Information Disclosure Statement

Responsive to item 1 of the Official Action, the corrected PTO-1449 form filed on April 29, 2004 refers back to an Information Disclosure Statement filed with the original application papers submitted January 16, 2004 which states that copies of the materials listed on the modified PTO-1449 form filed with that IDS may be found in the file of parent application Serial No. 10/062,720. As the examiner requests, copies of the foreign patent documents and the non-patent literature documents are provided with this response as an IDS – the $180.00 fee for considering this IDS is also paid.

Please in due course indicate that these documents have been considered by initialing, dating and returning to the undersigned a copy of the PTO-1449 form.

Included with the Official Action is an Interview Summary with respect to discussions between the examiner and the undersigned on July 23, 2004. Counsel confirms the statements contained in that document. A written requirement confirm the substance of the interview was issued on August 6, 2004 and responded to on August 20, 2004. In addition, a Statement of Substance of Interview was submitted on January 31, 2005.

Requirement for Restriction – Non-Elected Subject Matter

In the above instructions claims 21 through 25, directed to non-elected subject matter, have been canceled. It will be understood that this action is taken without disclaimer or without prejudice to a divisional application directed to the subject matter of these claims.

Discussion of Claim Amendments

The claims have been amended in order to more particularly point out and distinctly claim that which applicants regard as their invention and to advance prosecution generally. More specifically, the subject matter of claims 12-14 has been incorporated into claim 1. Claims

12-14 are now redundant and have been canceled. The dependencies of claims 15 and 16 have been adjusted to account for the amendments made above.

By the above amendments to claim 11, the active ingredient has been specified as "faropenem" or a pharmaceutically acceptable salt thereof. The amount of the active ingredient (0.1 to 10% by weight) has also been specified. Further, it has been made clear that the non-aqueous base used in the invention is hydrophobic.

The present invention addresses the problem that faropenem (i.e., (+)-(5R,6S)-6-[(R)-1-hydroxyethyl]-7-oxo-3-[(R)-2-tetrahydrofuryl]-4-thia-1-azabicyclo[3.2.0]hepto-2-ene-2-carboxylic acid) was not stable in a topical composition. Therefore, it was practically not possible to use faropenem in a topical composition such as an ointment to treat infectious diseases by topically applying faropenem to treat infected patients. The problem was solved by the unexpected finding that faropenem can be stably maintained in an ointment having a non-aqueous hydrophobic base. The surprisingly good stability is clearly shown in Table 1 of the specification.

Response to Prior Art-Based Rejections

In items 2-3 of the Official Action, claims 11-13 and 15-19 were rejected as allegedly being anticipated by the '906 reference. Claim 14 was not included in this rejection. As the subject matter of claim 14 has now been incorporated into claim 1, all of the remaining claims, which are dependent either directly or indirectly from claim 11, are free of this rejection on the basis of the examiner's comments in item 3 of the Official Action and listing of rejected claims.

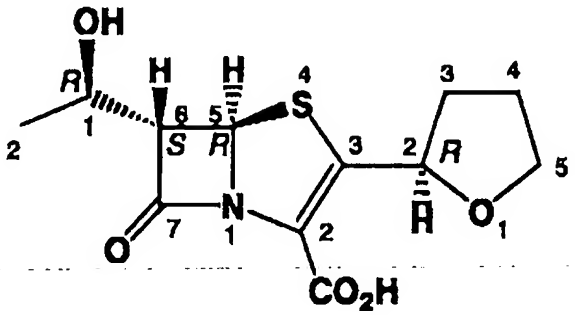
For completion of the record however counsel does wish to address the examiner's anticipation rejection on the deficiencies of the rejection itself.

To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art. *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997). Anticipation rejections are only proper when the "claimed subject matter is identically disclosed or described in 'the prior art,' without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972). Every element of the challenged claim must be disclosed within this single reference. *PPG Industries*

Inc. v. Guardian Industries Corp., 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation *Kloster Speedsteel AB v. Crucible Inc.* 23 USPQ 160 (Fed. Cir. 1986).

Thus, applicants' claims are patentable over each of the cited references since they each fail to disclose each element of applicants' claims.

Looking next at the underlying facts, it will be apparent that there is no anticipation. The compound of the Girijavallabhan et al reference (U.S. 4,411,906) has a fluoroalkylthio group in the 3-position; *see* the structure at column 1, line 15. In contrast, faropenem has a tetrahydrofuryl group in the same position as shown in the following formula:



Accordingly there is no anticipation and the rejection against claims 11-13 and 15-19 as allegedly being anticipated by Girijavallabhan et al is incorrect.

In items 4-5 of the Official Action claims 14 and 20 stand rejected as lacking patentability over a combination of two references. The argumentation submitted in item 5 of the Official Action in support of this rejection fails to address one of the necessary components, namely motivation to make the combination of documents cited and relied upon.

The U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)).

Addressing next this rejection on the basis of the documents themselves, Girijavallabhan et al relate to a novel penem compound which differs from faropenem, as explained above. Kari

et al (U.S. 5,654,451) relate to biologically active amino acids and peptides. Thus, these references do not teach or even remotely suggest the present invention which solved the problem of instability of faropenem in a topical composition by employing a non-aqueous hydrophobic base.

Miscellaneous Comments

Counsel has difficulty in understanding the examiner's comments on page 4, item 5, lines 6-9 of that portion which comment that "the antibiotic can also exist in the anhydride form ...". The examiner apparently misunderstands the term "expressed as free anhydride" as used in (previous) claim 14, now incorporated into claim 11. Claim 14 simply defines that the amount of faropenem in the ointment is from 0.1 to 10% by weight on the basis of the entire ointment, and that the amount is calculated in terms of fee anhydride form. Therefore, this feature of claim 14 does not mean that faropenem is used in free anhydride form, only that the concentration is recovered on the basis of the free anhydride.

Summary

Having fully responded to all of the pending objections and rejections contained in the current Action, applicants submit that the claims as above amended are free of the prior art and are in condition for allowance and solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is needed.

Reconsideration and favorable action are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

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